EXHIBIT F

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Marcella Chesney,
Plaintiffs,

v.

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S., L.L.C., SANOFI-AVENTIS, U.S., INC., and SANOFI-SYNTHELABO, INC.
Defendants.

MATSUMOTO, J.

POHORELSKY, M.J.

Case No. CV 11-3246

SUMMONS ISSUED

Plaintiff, by her attorneys, **PARKER WAICHMAN ALONSO LLP,** on behalf of herself individually, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $150,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

2. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

3. Venue in this action properly lies in the Eastern District of New York as the Defendants conduct substantial business in this district.

PARTY PLAINTIFF

4. Plaintiff, MARCELLA CHESNEY, is a natural person and is a resident of the State of TENNESSEE.

5. As result of using Defendants' PLAVIX, Plaintiff MARCELLA CHESNEY, was caused to suffer bilateral subdural hematomas on or about July of 2010.

6. Plaintiff, MARCELLA CHESNEY, was prescribed PLAVIX for a cerebral-vascular accident in or about March of 2010.

7. Plaintiff, MARCELLA CHESNEY used PLAVIX in the manner in which it was prescribed to her at or about the time she suffered bilateral subdural hematomas on or about July 2010.

8. In order to treat her bilateral subdural hematomas, plaintiff, MARCELLA CHESNEY, underwent a painful operation to drain the bilateral subdural hematomas.

9. Plaintiff, MARCELLA CHESNEY, was caused to sustain severe, permanent and life threatening personal injuries, pain, suffering, emotional distress, lifelong fear of premature death and the need for continued lifelong treatment and medications.

10. The injuries and damages sustained by Plaintiff, MARCELLA CHESNEY, were caused by Defendants' PLAVIX.

PARTY DEFENDANTS

11. Defendant, Bristol-Myers Squibb Company (hereinafter referred to as "BMS") is a pharmaceutical manufacturing and marketing company that partners with Sanofi-Aventis (now Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc.) to manufacture and market PLAVIX in the United States. The headquarters for Bristol-Myers Squibb Company is located at 345 Park Avenue, New York, New York, 10145-0037.

12. Defendant, Sanofi-Aventis U.S. L.L.C. is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market PLAVIX in the United States. The American base for Sanofi-Aventis U.S. L.L.C. is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey 08807-0912.

13. Defendant, Sanofi-Aventis U.S., Inc., is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market PLAVIX in the United States. The American base for Sanofi-Aventis U.S., Inc., is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey, 08807-0912.

14. Defendant, Sanofi-Synthelabo, Inc., is a Delaware corporation with its commercial headquarters at 90 Park Avenue, New York, New York, 10016. Sanofi-Synthelabo, Inc., did business as Sanofi Pharmaceuticals, Inc., and was the sponsor for an application for PLAVIX. Sanofi-Synthelabo, Inc., is an affiliate of Sanofi-Aventis, Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., that was instrumental in bringing PLAVIX to market.

15. The three Sanofi Defendants—Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. Inc., and Sanofi-Synthelabo, Inc., will be collectively referred to as "Sanofi" in this complaint.

FACTUAL BACKGROUND

16. This is an action for damages suffered by Plaintiffs as a direct and proximate result of the Defendants' negligence and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and/or sale of PLAVIX.

17. At all material times, PLAVIX was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the Defendants.

18. The Sanofi Defendants and BMS co-developed PLAVIX, applying in April 1997, for a rare *priority regulatory review*, by the U.S. Food and Drug Administration (FDA), which cleared the way for the Defendants to bring PLAVIX to market in November of 1997.

19. The rush to obtain FDA approval of PLAVIX is indicative of Defendants' emphasis on marketing and profit making over patient safety.

20. PLAVIX was heavily marketed directly to consumers through television, magazine and Internet advertising. It was touted as a "super-aspirin," that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin while being safer and easier on a person's stomach than aspirin. Those assertions have proven to be false.

21. The truth is, that BMS and Sanofi always knew, or if they had paid attention to the findings of their own studies, should have known, that PLAVIX was not more efficacious than aspirin to prevent heart attacks and strokes. More importantly though, Defendants knew or should have known that when taking PLAVIX, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder, or death far outweigh any potential benefit.

22. Still, BMS and Sanofi continued to exaggerate the results of their own studies and made false statements in their advertising and promotional materials for the purpose of increasing their profits from PLAVIX sales.

23. The profit at stake for the Defendants is enormous. By way of illustration, in 2005, PLAVIX, was the sixth top selling drug in the United States and the Defendants enjoy annual sales of PLAVIX totaling $3,800,000,000.00 (3.8 billion dollars).

24. BMS and Sanofi Defendants repeatedly thwarted the law and their duty to tell the public the truth about PLAVIX they were over-promoting for profit. The FDA issued numerous letters insisting these Defendants stop their misleading, over-promotional practices.

25. As examples, in 1998, the FDA requested the Defendants stop promoting PLAVIX for off-label use in patients receiving arterial stents. In the same reprimand, the FDA noted that not only were the Defendants' marketing PLAVIX to physicians for a treatment for which it had not been approved, but also were recommending that a non-FDA approved dosage nearly four (4) times that of other applications be given.

26. That same FDA warning criticized the Defendants' attempts at over-promotion of PLAVIX for unapproved use for lacking fair balance and failing to disclose any of the risks associated with its use. In particular, the FDA criticized that the Defendants were claiming to physicians, in their promotional letter, that PLAVIX was safe for use with other drugs. This, said the FDA, was overstating the safety profile of PLAVIX. In particular, its safety when combined with aspirin (known as "dual therapy") had not been established, yet Defendants were making a claim that the dual combination therapy of aspirin plus PLAVIX was safe. This claim has now been proven to be untrue in a recent study called CHARISMA (the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management and Avoidance Trial), which was reported in *The New England Journal of Medicine*, April 20, 2006.

27. Again in 1998, the FDA issued a letter demanding the Defendants immediately cease distribution of advertising materials that claimed that PLAVIX has been proven to be more effective than aspirin. The FDA criticized this marketing ploy as an overstatement of efficacy that is lacking in fair balance and unsubstantiated.

28. Undaunted, the Defendants were back in the business of hiding bad facts about their drug and fabricating more favorable information so they could sell large quantities of PLAVIX and make giant corporate profits. In 2001, the FDA was again forced to order Defendants to immediately cease distribution of promotional materials that made unsubstantiated claims about PLAVIX and was misleading. Specifically, the Defendants' promotional materials mislead consumers about their own study, called CAPRIE (Clopidogrel versus Aspirin in Patients at Rick of Ischemic Events). While the Defendants' trumped-up promotional material claimed that PLAVIX was 19.2% better than aspirin, the actual findings of the CAPRIE study were that PLAVIX was not proven to be significantly more effective than aspirin-providing a 2.9% reduction in ischemic events versus a 3.47% reduction of ischemic events for the study participants who had been given

aspirin. Defendants again claimed that the use of PLAVIX combined with aspirin was safe and effective, and again, the FDA forced Defendants to stop saying that because it had not been proven to be true.

29. In addition to misinforming physicians and the public through their advertising to consumers and promotional materials for doctors, Defendants' drug representatives have also misinformed physicians about the proper types of patients who should be given PLAVIX, the duration of its proper usage, and the applications for which it is safe and FDA approved.

30. Defendants, through, their drug representatives, and their promotional efforts, have encouraged physicians to prescribe PLAVIX to a broad population of people who would receive the same therapeutic benefit from aspirin alone, (without risking death) and to use PLAVIX for unapproved applications.

31. The result is that physicians are prescribing PLAVIX to people who could be cheaply and effectively protected against ischemic events by a simple aspirin, to pay approximately four dollars ($4.00) a day for a dose of PLAVIX.

32. Defendants' nearly eight-year run of lying to physicians and to the public about the safety and efficacy of PLAVIX for the sole purpose of increasing corporate profits has now been uncovered by scientific studies that reveal that not only is PLAVIX not worth its high price—it is dangerous.

33. The Chan study, written about in *The New England Journal of Medicine*, and named for the scientific researcher who conducted it, showed the fallacy of Defendants' assertion that PLAVIX is safer and more effective for patients who have a gastrointestinal intolerance to aspirin. The Chan study compared the effects of Aspirin and PLAVIX on patients who had previously had stomach ulcers that had healed. In that group, the incidence of recurring stomach bleeding was 8.6% in the PLAVIX group versus only .7% in the aspirin group. Dr. Chan recommended that the

prescribing guidelines for PLAVIX be changed so that the patients would not erroneously believe that PLAVIX is safer on the stomach than aspirin.

34. The Chan study also uncovered the fact that an aspirin a day plus esomeprazole (the generic name for a cheap, over the counter proton pump inhibitor like Prilosec) is far more cost effective for the consumer than paying for a four-dollar ($4.00) a day PLAVIX pill that greatly increases the risk of stomach bleeding.

35. Most recently, the CHARISMA trial uncovered another truth about PLAVIX. It found that PLAVIX plus aspirin (dual therapy) is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events. But more importantly, it found that in patients who do not have peripheral arterial disease (PAD) or acute coronary syndrome (ACS), PLAVIX plus aspirin (dual therapy) poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. In other words, in those patients without ACS or PAD, dual therapy with aspirin and PLAVIX does more harm than good.

36. Despite the growing body of scientific knowledge that the four-dollar ($4.00) PLAVIX pill was not much better than a four-cent-a-day aspirin, Defendants kept promoting it to the public and to physicians, using hyperbole and outright falsification in the process.

37. Plaintiff, MARCELLA CHESNEY, was prescribed PLAVIX on or about March of 2010 and continued on PLAVIX until July of 2010. On or about July of 2010, MARCELLA CHESNEY suffered a bilateral subdural hematomas, requiring bilateral burholes for evacuation of subdural and hospitalization all resulting from her ingestion of PLAVIX.

38. The label for PLAVIX drug products, known as the "Package Insert" was developed by the Defendants and accompanied all PLAVIX prescription drug products and/or samples and was published in the Physician's Desk Reference.

39. Drug labeling is to include accurate information concerning a drug's active and inactive ingredients, clinical pharmacology, indications, usage, efficacy, contraindications, warnings, precautions and side effects.

40. Defendants failed to fully, truthfully and accurately communicate the safety and efficacy of PLAVIX drug products and intentionally and fraudulently mislead the medical community, physicians, Plaintiffs' physicians and Plaintiffs about the risks associated with PLAVIX.

41. Defendants fraudulently and aggressively promoted PLAVIX drug products to physicians for use in patients, such as the Plaintiff, through medical journal advertisements, use of mass mailings, and direct communications, as well as other promotional materials including package inserts, physician desk reference, monographs and patient brochures, leaflets and hand outs as these materials downplayed the significance of the adverse effects of PLAVIX.

42. At all relevant times hereto, Defendants did not investigate the accuracy of the PLAVIX drug product labeling.

43. Defendants were negligent in failing to report published articles and overwhelming scientific evidence of the true effects described above to the FDA, healthcare providers and patients, including Plaintiffs.

44. Defendants were required to report literature, papers; and, to undertake action to reflect truthful and accurate information in its labeling and promotional materials and failed to do so.

45. Defendants are under a duty to ensure that their PLAVIX drug product labels are accurate.

46. Defendants failed to ensure its PLAVIX warnings to the medical community were accurate and adequate and breached this duty.

47. Defendants have a duty to conduct post market safety surveillance; to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by PLAVIX drug products, the medical community, Plaintiff's physician, Plaintiff and other foreseeable users and failed to fulfill this duty.

48. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of PLAVIX, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of their PLAVIX drug products.

49. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because Defendants failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by PLAVIX drug products to said persons and other foreseeable users.

50. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report significant data concerning the lack of efficacy and side effects associated with PLAVIX.

51. Defendants knew or should have known about the side effects, risks, misleading and inaccurate information contained in PLAVIX drug product labels and knowingly and intentionally withheld that information and or failed to report that information to the medical community, physicians, Plaintiffs, plaintiffs' physicians and other foreseeable users.

52. At all times material hereto, Defendants were aware of the serious side effects described herein which were caused by PLAVIX drug products and failed to fulfill the obligation to report and divulge said side effects, and in doing so, mislead the medical community, physicians,

Plaintiff's physicians, Plaintiff and other foreseeable users about the safety and efficacy of PLAVIX drug products.

53. At all times material hereto, Defendants knew or should have known that physicians and plaintiffs were unaware of or did not fully appreciate the seriousness of the risks associated with use of PLAVIX drug products and the lack of benefit of the drug.

54. At the time Defendants made the above-described representations, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true.

55. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Defendants' failure to correct false and misleading information it disseminated to physicians, which contained inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of PLAVIX.

56. In doing the acts alleged in this Complaint, Defendants acted with oppression, fraud, and malice and the Plaintiff is therefore entitled to punitive damages to deter Defendants and others from engaging in similar conduct in the future.

57. As a proximate result of the fraud and deceit of Defendants, Plaintiff, MARCELLA CHESNEY, sustained the injuries and damages as described in this Complaint.

58. Defendants have an absolute duty to disclose the true facts regarding the safety of PLAVIX drug products to the medical community, to physicians and their patients, which they negligently and/or intentionally failed to do.

59. Defendants have a duty to ensure that they had a reasonable basis for making the representations regarding the safety; efficacy, risks and benefits of PLAVIX were accurate which it negligently and/or intentionally failed to do.

60. The Plaintiff would not have suffered the aforementioned injuries but for the above misrepresentations or omissions of Defendants.

61. Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiff's damages.

62. A reasonably competent physician who prescribed PLAVIX and a reasonably competent Plaintiff who consumed PLAVIX would not realize its dangerous condition.

63. The reasonably foreseeable use of PLAVIX drug products involved substantial dangers not readily recognizable by Plaintiff's physicians, who acted as ordinary, reasonable and prudent physicians would, when prescribing PLAVIX to ordinary, reasonable and prudent patients, like the Plaintiff.

64. As a direct and proximate result of the aforesaid acts of and/or omissions by the Defendants, Plaintiff, has:

(a) Suffered severe and permanent injuries, which she will be forced to endure for the remainder of her life;

(b) Suffered physical impairment and disfigurement;

(c) Suffered physical pain and suffering;

(d) Suffered mental pain and suffering;

(e) Suffered from loss of enjoyment of life;

(f) Incurred and will continue to incur various sums of money for past, present and future medical expenses associated with monitoring and treating Plaintiffs injuries; and

(g) Incurred attorney's fees and expenses of litigation related to this action.

65. Defendants' actions were intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences and acted only out of self interest and personal gain and evidenced a specific intent to cause harm to the Plaintiff.

66. Plaintiff's serious and permanent injuries, came about as a foreseeable and proximate result of the Defendants' dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the effects of exposure and ingestion of PLAVIX to the medical community, physicians, Plaintiff's physician, Plaintiff and other foreseeable users of PLAVIX.

67. Plaintiff has experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain and suffering, psychological injury and other injuries and damages due to the injuries suffered caused by the ingestion of Defendants' PLAVIX drug products.

FEDERAL REQUIREMENTS

68. Defendants had an obligation to comply with the law in the manufacture, design, and sale of PLAVIX.

69. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*

70. With respect to the prescription drug PLAVIX, the Defendants, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. The prescription drug PLAVIX is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. The prescription drug PLAVIX is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls

below the standard set forth in the official compendium for PLAVIX and such deviations are not plainly stated on their labels.

c. The prescription drug PLAVIX is misbranded pursuant to 21 U.S.C. §352 because, among other things, its labeling is false or misleading.

d. The prescription drug PLAVIX is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The prescription drug PLAVIX is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. The prescription drug PLAVIX is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The prescription drug PLAVIX does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or

uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. The prescription drug PLAVIX is misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of PLAVIX cause and the need for regular and/or consistent monitoring to ensure that a potential heart attack, stroke, blood disorder, and/or abnormal bleeding and has not developed.

k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug PLAVIX.

l. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug PLAVIX are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.

m. The prescription drug PLAVIX is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

n. The prescription drug PLAVIX is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

o. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug PLAVIX and other drugs in the same pharmacologically active and chemically related class.

p. The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop heart attacks, strokes, blood disorders, abnormal bleeding and even death in an unacceptably high number of its users; and yet the Defendants failed to list those developments before the other adverse reactions on the labeling of the prescription drug PLAVIX.

q. The prescription drug PLAVIX is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. The prescription drug PLAVIX violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and

strength and meets the quality and purity characteristic that they purport or are represented to possess.

s. The prescription drug PLAVIX violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. The prescription drug PLAVIX violates 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. The prescription drug PLAVIX violates 21 CFR § 211.165 in that the prescription drug PLAVIX fails to meet established standards or specifications and any other relevant quality control criteria.

v. The prescription drug PLAVIX violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug PLAVIX were not followed.

w. The prescription drug PLAVIX violates 21 CFR § 310.303 in that the prescription drug PLAVIX is not safe and effective for its intended use.

x. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug PLAVIX as soon as

possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.

z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug PLAVIX, and evaluating the cause of the adverse event.

aa. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

cc. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report followup."

dd. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug PLAVIX or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

71. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendants negligent *per se*.

FIRST CAUSE OF ACTION
AGAINST THE DEFENDANTS
NEGLIGENCE

72. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

73. Defendants had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of PLAVIX to ensure the safety of PLAVIX and to ensure that the consuming public, including the Plaintiff and Plaintiff's physicians and agents, obtained accurate information and instructions for the use of PLAVIX.

74. Defendants owed a duty toward foreseeable users of PLAVIX drug products to exercise reasonable care to ensure that PLAVIX drugs were reasonably safe for ordinary and intended uses, and specifically, *inter alia*, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks increased heart attack or stroke, blood disorders and excessive bleeding described above.

75. Defendants failed to exercise reasonable care in testing PLAVIX for side effects in ordinary and foreseeable users; and failed to disseminate to physicians accurate and truthful information concerning the effects of PLAVIX; thus, physicians were not able to make informed choices concerning the use of PLAVIX drug products.

76. Defendants failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of PLAVIX into the stream of commerce in that Defendants knew or should have known that PLAVIX drug products created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.

77. The dangerous propensities of PLAVIX drug products as referenced above, were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time it distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe PLAVIX for the Plaintiff and other patients, similarly situated.

78. The information Defendants disseminated to physicians concerning PLAVIX drug products was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.

79. As a proximate result, the Plaintiff suffered grievous bodily injuries and consequent economic and other losses when they ingested PLAVIX.

80. The Defendants was negligent, and breached their duties of reasonable care to the Plaintiff with respect to PLAVIX drug products in one or more of the following respects:

(a) Despite knowledge of hazards and knowledge that the product was frequently prescribed for the use, Defendants failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of PLAVIX;

(b) Defendants failed to conduct adequate testing;

(c) Despite knowledge of hazards, Defendants failed to conduct adequate post-marketing surveillance to determine the safety of the product;

(d) Despite knowledge of hazards, Defendants failed to adequately warn Plaintiff's physicians or the Plaintiff that the use of PLAVIX drug products could result in severe side effects as described above;

(e) Despite the fact that the Defendants knew or should have known that their PLAVIX drug products caused unreasonably dangerous side effects, Defendants failed to adequately disclose the known or knowable risks associated with PLAVIX as set forth above; Defendants willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of the Plaintiffs safety and/or welfare;

(f) Defendants failed to design, develop, implement, administer, supervise and monitor its clinical trials for PLAVIX; and

(g) Defendants, in its promotion of PLAVIX, were overly aggressive and deceitful, and promoted PLAVIX in a fraudulent manner, despite evidence known to Defendants that PLAVIX was dangerous.

81. As a direct and proximate result of the wrongful acts of the Defendants, the Plaintiff developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

82. The negligence, carelessness, and the willful and wanton misconduct of the Defendants was a proximate cause of Plaintiff's harms and injuries that the Plaintiff suffered and will continue to suffer.

83. In the alternative, Defendants' acts of omissions and concealment of material facts of the design and manufacturing defects were made with the understanding that patients and physicians would rely upon such statements when choosing PLAVIX drug products.

84. Furthermore, the economic damages and physical harm caused by Defendants' conduct would not have occurred had Defendants exercised the high degree of care imposed upon it.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for her injuries and which will deter the Defendants and others from like conduct. Further, because Tennessee law requires Plaintiffs to include at the time a products liability lawsuit is filed a request for damages in an amount-certain, Plaintiff requests that the jury in its discretion find in favor of Plaintiff in an amount not less than $3,000,000 against Defendants.

AS AND FOR THE
SECOND CAUSE OF ACTION
AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN)

85. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

86. At all relevant times the Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling PLAVIX.

87. PLAVIX is defective and unreasonably dangerous to consumers.

88. At all times mentioned in this Complaint PLAVIX was defective and/or unreasonably dangerous to Plaintiffs and other foreseeable users at the time it left the control of the Defendants.

89. PLAVIX is defective in its design or formulation in that when it left the hands of the Defendants, its foreseeable risks exceed the benefits associated with its design and formulation and/or it was more dangerous than an ordinary consumer would expect.

90. The foreseeable risks associated with the design or formulation of PLAVIX, include, but are not limited to, the fact that the design or formulation of PLAVIX is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.

91. At all times material to this action, PLAVIX was expected to reach, and did reach consumers in the State of Tennessee and throughout the United States, including the Plaintiff, without substantial change in the condition in which it was sold.

92. Defendants, developed, marketed and distributed PLAVIX drug products to the general public even after learning of the design and manufacturing defects that threatened the intended

use of PLAVIX.

93. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that PLAVIX created a high risk of bodily injury and serious harm.

94. The dangerous propensities of PLAVIX drug products were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time said Defendants distributed, supplied, or sold PLAVIX, and not known to ordinary physicians who would be expected to prescribe PLAVIX for their patients.

95. PLAVIX drug products, as distributed, were defective and unreasonably dangerous inasmuch as PLAVIX were not accompanied by warnings and instructions that were appropriate and adequate to render PLAVIX reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of PLAVIX.

96. In order to advance Defendant's own pecuniary interests, Defendants intentionally proceeded with the manufacturing, the sale and distribution, and marketing of PLAVIX drug products with knowledge that consumers would be exposed to serious danger.

97. At all times material to this action, PLAVIX was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a "defective" and "unreasonably dangerous" condition, at the time it was placed in the stream of commerce in ways that include, but are not limited to one or more of the particulars:

a. At the time PLAVIX left the control of the Defendants PLAVIX was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because PLAVIX breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiffs' physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiffs seek recovery herein;

b. PLAVIX drug products were not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time PLAVIX left the possession of the Defendants, and that such risks clearly outweighed the utility of PLAVIX therapy or its therapeutic benefits, and subjected Plaintiffs to the risk of suffering avoidable

heart attacks, strokes, blood disorders, abnormal bleeding and even death in an unacceptably high number of its users;

c. At the time PLAVIX left the control of the Defendants PLAVIX possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time PLAVIX left the possession of the Defendants. Specifically, although the Defendants were well aware that PLAVIX products could potentially cause severe side effects;

d. The Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of PLAVIX taking into account the characteristics of the PLAVIX, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases PLAVIX, such as the Plaintiff;

e. PLAVIX manufactured and supplied by the Defendants were further defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risks of injury from PLAVIX drug products associated with the use as commonly prescribed, Defendants failed to promptly respond to and adequately warn about the risks of suffering avoidable heart attacks, strokes, blood disorders, abnormal bleeding and death associated with the use of PLAVIX;

f. When placed in the stream of commerce of commerce, PLAVIX was defective in design and formulation, making the use of PLAVIX more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other similar drugs on the market including Aspirin; and

g. PLAVIX was insufficiently tested.

98. The Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which the Plaintiff seeks recovery.

99. The Defendants knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of PLAVIX that caused the damages for which Plaintiff seeks recovery.

100. The reasonably foreseeable use of PLAVIX involved substantial dangers not readily recognizable by the ordinary physician who prescribed PLAVIX or the patient, including the Plaintiff, who consumed PLAVIX drug products.

101. The Defendants knew that PLAVIX drug products were to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that PLAVIX was not properly prepared nor accompanied by adequate warnings of the dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

102. Plaintiff and Plaintiff's physicians did not know, nor had reason to know, at the time of the use of Defendants' PLAVIX drug products, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

103. The above defects caused serious injuries to Plaintiff when PLAVIX was used in its intended and foreseeable manner, and in the manner recommended by the Defendants and/or in a non-intended manner that was reasonably foreseeable.

104. In addition, at the time that PLAVIX left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of PLAVIX. These safer designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing PLAVIX's utility.

105. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

106. For the above reasons, the Defendants are strictly liable under New York product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for her injuries and which will deter the Defendants and others from like conduct. Further, because Tennessee law requires Plaintiffs to include at the time a products liability lawsuit is filed a request for damages in an amount-certain, Plaintiff requests that the jury in its discretion find in favor of Plaintiff in an amount not less than $3,000,000 against Defendants.

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT)

107. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

108. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling PLAVIX.

109. At all times material to this action, PLAVIX was expected to reach, and did reach consumers in the State of New York and throughout the United States, including the Plaintiff, without substantial change in the condition from which it was sold.

110. At all times material to this action, PLAVIX was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways that include, but are not limited to, one or more of the following particulars posing a serious risk of injury and death.

a. When placed in the stream of commerce, PLAVIX contained manufacturing defects that rendered the product unreasonably dangerous;

b. PLAVIX's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. PLAVIX was not made in accordance with the Defendants' product specifications or performance standards; and

d. PLAVIX's manufacturing defects existed before it left the control of the Defendants.

111. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

112. For the above reasons, the Defendants are strictly liable under New York product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for her injuries and which will deter the Defendants and others from like conduct. Further, because Tennessee law requires Plaintiffs to include at the time a products liability lawsuit is filed a request for damages in an amount-certain, Plaintiff requests that the jury in its discretion find in favor of Plaintiff in an amount not less than $3,000,000 against Defendants.

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY - FAILURE TO WARN)

113. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

114. PLAVIX was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiff and/or her health care providers, of the dangerous risks and reactions associated with PLAVIX, including but not limited to its propensity to cause avoidable strokes, heart attacks, abnormal bleeding, and other serious injuries and side effects despite the Defendants' knowledge of the increased risk of these injuries over similar drugs such as aspirin.

115. PLAVIX was defective due to inadequate post-marketing warnings or instruction because after Defendants knew or should have known of the risk and danger of serious bodily harm and/or death from the use of PLAVIX, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and/or death.

116. Plaintiff was prescribed and used PLAVIX for its intended purpose.

117. The Plaintiff could not have known about the dangers and hazards presented by PLAVIX.

118. The warnings that were given by the Defendants were not accurate, clear, complete and/or were ambiguous.

119. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of stroke, heart attack, bleeding and other serious injuries and side effects, and

failed to instruct physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk.

120. The warnings that were given by the Defendants failed to properly warn consumers of the increased risk of stroke, heart attack, bleeding, and other serious injuries and side effects.

121. The Plaintiff, individually and through her prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of the Defendants. The Defendants had a continuing duty to warn the Plaintiff of the dangers associated with PLAVIX. Had the Plaintiff received adequate warnings regarding the risks of PLAVIX, they would not have used PLAVIX.

122. As a direct and proximate result of PLAVIX's defective and inappropriate warnings, the Plaintiff suffered severe physical injuries and damages as described above.

123. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

124. For the above reasons, the Defendants are strictly liable under New York product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for her injuries and which will deter the Defendants and others from like conduct. Further, because Tennessee law requires Plaintiffs to include at the time a products liability lawsuit is filed a request for damages in an amount-certain, Plaintiff requests

that the jury in its discretion find in favor of Plaintiff in an amount not less than $3,000,000 against Defendants.

FIFTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

125. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

126. Defendants' expressly warranted to the Plaintiff that PLAVIX drug products were safe and effective.

127. In response to these promises and express statements, Plaintiff and plaintiff's physicians relied on such affirmations and warranties.

128. PLAVIX drug products do not conform to those express representations in light of recently discovered disclosures and information previously withheld by Defendants. Defendants' express warranty through its false statements failed to disclose design, manufacturing and safety defects inherent in PLAVIX.

129. Defendants breached its warranties of PLAVIX by continuing sales and marketing campaigns highlighting the safety of its PLAVIX drug products, while it knew of the design, manufacturing and safety defects and the risk of heart attacks, stroke, excessive bleeding and blood disorders, as described throughout this Complaint.

130. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of

Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for her injuries and which will deter the Defendants and others from like conduct. Further, because Tennessee law requires Plaintiffs to include at the time a products liability lawsuit is filed a request for damages in an amount-certain, Plaintiff requests that the jury in its discretion find in favor of Plaintiff in an amount not less than $3,000,000 against Defendants.

AS AND FOR THE
SIXTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

131. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

132. The Defendants knew that most physicians who prescribed PLAVIX drug products were not aware of the serious side effects as described herein associated with use of PLAVIX. The Defendants also knew that the risks of said side effects were much greater than most physicians realized. By failing to give adequate warnings about these side effects and the risk of the use that is associated with those side effects, the Defendants breached implied warranties of merchantability and fitness for the ordinary use of PLAVIX.

133. At all times mentioned in this Complaint, the Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold PLAVIX drug products and prior to the time PLAVIX was used by Plaintiffs, the Defendants impliedly warranted to Plaintiff and to Plaintiff's physicians that PLAVIX were of merchantable quality and safe and fit for the use for which PLAVIX were intended.

134. Plaintiff relied on the skill and judgment of the Defendants in using PLAVIX drug products.

135. PLAVIX drug products were not safe and were unfit for their intended use, nor were PLAVIX of merchantable quality, as warranted by the Defendants, in that PLAVIX had very dangerous propensities when put to intended use and would cause severe injury to the user. PLAVIX drug products were not properly prepared nor accompanied by adequate warnings of PLAVIX's dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution. As a result, PLAVIX drug products proximately caused Plaintiffs to sustain damages and injuries as alleged in this Complaint.

136. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for her injuries and which will deter the Defendants and others from like conduct. Further, because Tennessee law requires Plaintiffs to include at the time a products liability lawsuit is filed a request for damages in an amount-certain, Plaintiff requests that the jury in its discretion find in favor of Plaintiff in an amount not less than $3,000,000 against Defendants.

SEVENTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
(FRAUDULENT MISREPRESENTATION)

137. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

138. Defendants had actual knowledge of facts, which demonstrated that representations in the package insert, and/or the PDR monograph, and/or literature, and/or other mediums that the Defendants distributed concerning their PLAVIX drug products were false and misleading. Defendants had an absolute duty to disclose the true facts regarding the safety of PLAVIX to physicians and their patients and the medical community, which they negligently failed to do. Furthermore, Defendants had a duty to ensure that they had a reasonable basis for making the representations described above, to exercise reasonable care in making those representations, to accurately make those representations, and to not make misrepresentations concerning PLAVIX, all of which Defendants failed to do.

139. Important information regarding the risk of PLAVIX was in the exclusive control of Defendants and was exclusively known by Defendants. In the furtherance of Defendants' own interests, Defendants disseminated false information regarding PLAVIX to physician and plaintiffs and did so knowing that the safety of PLAVIX depended on the accuracy of that information. Further, Defendants knew and expected that recipients of that information would rely on the information that the recipients would take action based upon the information, and that individuals would be put in peril by such actions and that those individuals would suffer physical harm as a result.

140. Defendants expressly and/or impliedly represented to Plaintiff, Plaintiff's physicians, the medical community, and members of the general public that their PLAVIX drugs were safe for

use. The representations by Defendants were, in fact, false. The true facts were that PLAVIX was not safe for its intended use and was, in fact, dangerous to the health and body of the Plaintiff.

141. Defendants made the above-described representations with no reasonable grounds for believing them to be true. Defendants did not have accurate or sufficient information concerning these representations and they failed to exercise reasonable care both in ascertaining the accuracy of the information contained in those representations and in communicating the information.

142. The aforementioned misrepresentations or omissions were made to the Plaintiff, and Plaintiff's physicians, and the medical community, all of whom justifiably and foreseeably relied on those representations or omissions. Plaintiff would not have suffered injuries but for the above misrepresentations or omissions of Defendants. Thus, Defendants and Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiff's damages.

143. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for her injuries and which will deter the Defendants and others from like conduct. Further, because Tennessee law requires Plaintiffs to include at the time a products liability lawsuit is filed a request for damages in an amount-certain, Plaintiff requests

that the jury in its discretion find in favor of Plaintiff in an amount not less than $3,000,000 against Defendants.

EIGHTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
(FRAUDULENT CONCEALMENT)

144. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

145. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of PLAVIX for its intended use.

146. Defendants knew or were reckless in not knowing that its representations were false.

147. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

a. that PLAVIX was not safe;

b. that the risks of adverse events with PLAVIX were high;

c. that the risks of adverse events with PLAVIX were not adequately tested and/or known by Defendants;

d. that Defendants were aware of dangers in PLAVIX, in addition to and above and beyond those associated with alternative medications;

e. that PLAVIX was defective, and that it caused dangerous side effects;

f. that patients needed to be monitored more regularly than normal while using PLAVIX;

g. that PLAVIX was manufactured negligently;

h. that PLAVIX was manufactured defectively;

i. that PLAVIX was manufactured improperly;

j. that PLAVIX was designed negligently;

k. that PLAVIX was designed defectively; and

l. that PLAVIX was designed improperly.

148. Defendants were under a duty to disclose to Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of PLAVIX, including but not limited to the heightened risks of heart attacks, stroke, excessive bleeding and blood disorders and/or death.

149. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used PLAVIX, including the Plaintiff, in particular.

150. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of PLAVIX was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and her physicians, hospitals and healthcare providers into reliance, continued use of PLAVIX, and actions thereon, and to cause them to purchase, prescribe, and/or dispense PLAVIX and/or use the product.

151. Defendants knew that Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding PLAVIX, as set forth herein.

152. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

153. As a result of the foregoing acts and omissions the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart attacks, stroke, excessive bleeding and blood disorders and/or sudden death, as well as other

severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

154. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper. Further, because Tennessee law requires Plaintiffs to include at the time a products liability lawsuit is filed a request for damages in an amount-certain, Plaintiff requests that the jury in its discretion find in favor of Plaintiff in an amount not less than $3,000,000 against Defendants.

NINTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
(NEGLIGENT MISREPRESENTATION)

155. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

156. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, PLAVIX, had been tested and found to be a safe and effective form of therapy.

157. The representations made by Defendants were, in fact, false.

158. Defendants failed to exercise ordinary care in the representation of PLAVIX, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of

said product into interstate commerce in that Defendants negligently misrepresented PLAVIX's high risk of unreasonable, dangerous side effects.

159. Defendants breached their duty in representing PLAVIX's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

160. As a result of the negligent misrepresentations of the Defendants set forth hereinabove, said Defendants knew and were aware or should have known that PLAVIX had been insufficiently tested, and/or had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including, inter alia, heart attacks, stroke, excessive bleeding and blood disorders and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature.

161. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper. Further, because Tennessee law requires Plaintiffs to include at the time a products liability lawsuit is filed a request for damages in an amount-certain, Plaintiff requests that the jury in its discretion find in favor of Plaintiff in an amount not less than $3,000,000 against Defendants.

TENTH CAUSE OF ACTION
AGAINST THE DEFENDANTS
(FRAUD AND DECEIT)

162. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

163. Defendants conducted research and used PLAVIX as part of their research.

164. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including, but not limited to, assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that PLAVIX was safe and effective for use.

165. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

166. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her respective healthcare providers and/or the FDA.

167. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including, but not limited to, reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

168. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug PLAVIX was safe and effective for use.

169. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug PLAVIX carried the same risks, hazards, and/or dangers as other alternative medications.

170. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that PLAVIX was as potentially injurious to the health and/or safety of its intended use as other alternative medications.

171. These representations were all false and misleading.

172. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that PLAVIX was not safe.

173. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of PLAVIX, specifically, but not limited to PLAVIX not having dangerous and serious health and/or safety concerns.

174. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff, regarding the safety of PLAVIX.

175. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of PLAVIX and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use PLAVIX.

176. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that PLAVIX was fit and safe for its intended use.

177. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that PLAVIX was fit and safe for use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other alternative medications.

178. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that PLAVIX did not present serious health and/or safety risks.

179. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that PLAVIX did not present health and/or safety risks greater than alternative forms of medication.

180. That these representations and others made by Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

181. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe PLAVIX.

182. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of PLAVIX to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

183. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of PLAVIX by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of PLAVIX.

184. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on PLAVIX and/or that her respective healthcare providers would dispense, prescribe, and/or recommend the same.

185. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

186. Defendants utilized direct to consumer advertising to market, promote, and/or advertise PLAVIX.

187. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendants' drug PLAVIX.

188. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of PLAVIX.

189. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

190. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of PLAVIX, Plaintiff would not have purchased, used and/or relied on Defendants' drug PLAVIX.

191. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

192. As a result of the foregoing acts and omissions Plaintiff was caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, heart attacks, stroke, excessive bleeding and blood disorders and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

193. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper. Further, because Tennessee law requires Plaintiffs to include at the time a products liability lawsuit is filed a request for damages in an amount-certain, Plaintiff requests that the jury in its discretion find in favor of Plaintiff in an amount not less than $3,000,000 against Defendants.

TENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(CONSUMER FRAUD - VIOLATION OF GBL §§ 349 and 350)

194. Plaintiff incorporates by reference the paragraphs above, as though fully set forth herein.

195. The Defendants acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including Plaintiff MARCELLA CHESNEY herein and her physicians and medical providers, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of PLAVIX, in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to prescribe PLAVIX to patients/consumers such as the Plaintiff MARCELLA CHESNEY herein. By reason of the Defendants' unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff MARCELLA CHESNEY herein, were caused to suffer ascertainable loss of money and property and actual damages.

196. The Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

197. The Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

198. The Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the

subject product, in violation of New York General Business Law ("GBL") §§ 349 and 350.

199. New York has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. The Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when the Defendants knew it was defective and dangerous, and by other acts alleged herein.

200. The Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff MARCELLA CHESNEY.

201. As a direct and proximate result of the Defendants' violations of GBL §§ 349 and 350, Plaintiff has suffered damages, for which she is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

202. As a direct and proximate result of Defendants' conduct, the Plaintiff used PLAVIX and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future..

203. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

204. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

ELEVENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(PUNITIVE DAMAGES)

205. At all times material hereto, the Defendants knew or should have known that PLAVIX was inherently more dangerous with respect to the risk of heart attack, stroke, excessive bleeding and blood disorders and/or sudden death.

206. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

207. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety and efficacy of the subject product.

208. At all times material hereto, the Defendants knew and recklessly disregarded the fact that PLAVIX was subject to an increased risk of heart attack, stroke, excessive bleeding and blood disorders and/or sudden death with far greater frequency than safer alternative medications.

209. Notwithstanding the foregoing, the Defendants continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative medications.

210. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm.

211. The Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiff and her physician of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

212. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the Plaintiff suffered severe injuries as set forth above.

213. The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

214. The Plaintiff seeks actual and punitive damages from the Defendants as alleged

herein.

215. Further, because Tennessee law requires Plaintiff to include, at the time a products liability lawsuit is filed, a request for damages in an amount-certain, Plaintiff requests that the jury in its discretion find in favor of Plaintiff in an amount not less than $3,000,000 against Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law but in any event in an amount not less than $3,000,000.00 for each and every individual Cause of Action set forth against Defendants herein;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

Respectfully Submitted,

PARKER WAICHMAN ALONSO LLP

By:_____

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Dated: July 5, 2011

Attorneys for Plaintiff Marcella Chesney

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Respectfully Submitted,

PARKER WAICHMAN ALONSO LLP

By: _____
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Dated: July 5, 2011